REMARKS

Support in the Specification for a Jet Injector and Effect of Preamble

The specification is amended to include the disclosure of the jet injection device in the summary of the invention, as disclosed in the Abstract of the originally filed specification.

Claims 1-17, 9-13, and 15-17 were rejected under 35 U.S.C. § 112, first paragraph with the allegation that the specification does not mention a "jet injector". As mentioned on page 7 of the previous amendment, this is disclosed in the abstract of the originally filed specification. For clarity, this disclosure has also been added to page 2 of the specification. As provided in 37 C.F.R. 1.77(b), the specification includes the abstract. Even the MPEP is clear that the abstract is considered to be "a part of the specification for purposes of compliance with paragraph 1 of 35 U.S.C. 112 . . . ." M.P.E.P. 608.01(b) (Citations omitted). Consequently, withdrawal of this rejection is respectfully requested.

Further with regard to the recitation of a jet injector, the Examiner argued that this recitation in the preamble was not given patentable weight and cited 1976 and 1951 case law in alleging that the term "jet injector" somehow merely relates to an intended use. The recitation of "A jet injector" is quite definitely structural and significantly affects the structural recitations in the body of the claim. One of ordinary skill in the art understands that a jet injector involves significant structural features, including firing and trigger mechanisms, as well as hardier construction of materials that need to withstand the high pressures, which includes the elements recited in the body of the claim. Specifically, the recited tube, needle, and stoppers would have a different and much stronger construction in a jet injector than in a hand operated syringe, for instance. Consequently, the term, "jet injector," in the preamble is a positively recited recitation from which the structures of the claim body depend.

As explained recently by the U.S. Court of Appeals for the Federal Circuit, the preamble needs to be considered as limiting the claim if it recites essential structure or if it is necessary to give life, meaning, and vitality to the claim. "Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art may indicate that the preamble is a claim limitation because the preamble is used to define the claimed invention." *In re Cruciferous Sprout Litigation*, 64 U.S.P.Q.2d 1202, 1204 (Fed. Cir. 2002)(citations omitted). In the present case, the preamble is structural as explained above;

gives life, meaning, and vitality to the claim because it defines a different type of injector than a manual syringe; and should be given weight since the Applicant is specifically using it to define the claimed invention.

For the sake of facilitating the prosecution, however, claim 1 has been amended to recite that the injector is a jet injection in the claim body. The subject matter of claim 1 prior to this amendment now appears, however, in claim 30 in unamended form, and must be considered with patentable weight given to the preamble.

The Examiner's Burden Was Not Met
in Withdrawing Claims 18-22 from Consideration

In the office action, the method claims 18-22 were once again not considered and have been withdrawn from consideration by the Examiner, who has still not satisfied the burden required by M.P.E.P. § 806.05(e). The present office action merely recites several M.P.E.P. rules, which the Applicants do not contest. However, the office action has not addressed Applicants' indication that such a burden has not been established.

Specifically, and as previously explained in the last amendment, M.P.E.P. § 806.05(e) applies to find where there is distinctness between process and apparatus claims. It is not enough that one set of claims be directed to a method or process while another is directed to an apparatus to find them distinct and issue a restriction requirement. The test of section 806.05(e) must first be met, and the burden of making a proper showing under this section falls squarely on the Examiner, who must "provide reasonable examples that recite material differences," between the claim groups. M.P.E.P. § 806.05(e). No example, reasonable or otherwise, was provided in issuing the still contested restriction requirement.

In this particular case, where a process and an apparatus for its practice are alleged to be distinct, a one-way distinctness is needed to support a distinctness requirement:

> Process and apparatus for its practice can be shown to be distinct inventions, if either or both of the following can be shown: (A) that the process *as claimed* can be practiced by another materially different apparatus or by hand; or (B) that the apparatus *as claimed* can be used to practice another and materially different process.
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> . . .
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> The burden is on the examiner to provide reasonable examples that recite material differences.

M.P.E.P. § 806.05(e) (emphasis original).

The only text received from the Examiner about the differences between the claim groups is that "Claims 18-22 are drawn to a method of injecting a medicament and not to the apparatus (medicament cartridge) itself. This statement by no means satisfies the Examiner's burden of showing how the section 806.5(e) test is met.

In fact, the process claims 18-22 do no meet the one-way test with respect to the apparatus claims. Claims 1 and 18 have very similar recitations to the extent there is no reasonable way to practice the method with a materially different apparatus, and there is no reasonable way to use the apparatus to practice a materially different method.

Consequently, even though the Applicant is not contesting that a non-express election can be fixed by action of the claims or by original claims, the groups of claims are not properly restrictable since they are not distinct under the appropriate rule, and the Examiner has not satisfied the required burden to make such a restriction.

Claims 23-28 Should Be Considered

The Examiner withdrew previously added claims 23-28 from consideration with the statement that Applicant confirmed that these are supported by the embodiment of Fig. 1, which is a non-elected species. This statement implies that the applicant intended to qualify these claims as belonging only to that species. This is not the case.

When these claims were added, Applicant merely indicated that an example of support for them was found in the embodiment of Fig. 1, that embodiment being the most basic. No assertion was made that these claims are not also supported by the elected species. A simple reading of the added claims reveals without a doubt that they are also supported by the embodiment of Figs. 7-10. No statement was ever made that they are not, and their examination cannot be merely avoided by arbitrarily coloring an applicants statement of where but one example of support can be found as if it were a statement of whether the claims apply to or are generic to the elected species.

Specifically, the elected species is configured for jet injecting the medicament from the fluid pathway, as defined in claim 23; configured to substantially prevent any other medicament contained in the cartridge from contacting the needle prior to firing the jet injector, as recited in claim 24; has the first stop that is slideable within the tube, as recited in claim 25; has a medicament cartridge configured so that all of the medicament of the cartridges injected together, as recited in claim 27; and have the needle in fixed association

with the second end of the tube, with the first stopper being free of any device to puncture another of the stopper, as recited in claim 28. Claim 26 is also directed to the elected species since it defines that the medicament cartridge comprises only two stoppers that contain all of the medicament there between. As explained on pages 6 and 7 of the application, all of the medicament is contained in the first chamber 38, which is defined between only two stoppers. The second chamber 34, shown in Fig. 7 is being disposed between stoppers 30 and 22, does not contain any medicament in Fig. 7, but instead contains a diluent.

Hence, no admission or statement was ever made by the applicants that the new claims were not directed to the elected species, and analysis of each of claims 23-28 reveals that they do in fact directly recite features supported and elected species. Applicants are thus entitled to have these claims examined presently.

Substantive Rejections

Claims 1-3, 6, 7, 9-13, 16, and 29 were rejected under 35 U.S.C. § 102(b) as anticipated by Richmond. Claims 1, 4, and 5 were rejected under section 102(b) as anticipated by Huber. Claim 15 was rejected under 35 U.S.C. § 103(a) over Richmond in view of Vetter '490, and claim 17 was rejected under section 103(a) as obvious over Huber in view of Tanaka. None of claims 18-22 have been rejected, but they should have been and presently should be considered, as explained above.

All of the claims are directed to a jet injector, whether by virtue of the preamble or by virtue of a recitation in the body of the claim. It is well known in the art that jet injectors inject medicaments by creating a high speed jet of the medicament that penetrates the tissue of the patient as a jet to a significant distance beyond the end of the injector. Some jet injectors are called needle-assisted jet-injectors because then use a needle to penetrate the patient tissue by a short distance, and the energy created in the jet is used to fire the medicament significantly deeper into the tissue. It is also known that jet injectors require certain components to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These components include, for instance, an energy source to drive the plunger when the injector is fired, a trigger to allow a user to fire the injector, and carefully dimensioned and configured jet nozzle to efficiently form the high speed jet. Due to the high speed and pressure requirements for jet injectors, they are not powered by pressing directly on a plunger by hand.

New claim 23 further clarifies that the jet injector is configured for jet injection of the medicament from the fluid pathway.

Both Richmond and Huber are directed to syringes, and neither teaches or suggests a jet injector, which is defined in claim 1. In particular, Richmond discloses a sequential delivery syringe with a plurality of stoppers with piercing devices to sequentially deliver different solutions in the various compartments, one after the other. The plunger of the syringe is powered by hand. There is no motivation to combine this teaching with any jet injector because a slow delivery of each solution is a function of the structure of this device. The sequential delivery of the drugs in each compartment would lead to undesirable pulsing in the intensity of a jet, which could hinder precise delivery to a desired depth in the tissue. Also, the series of thin needles of the Richmond piercing devices and the flow path through the interior of each stopper produces a significant loss of energy, that would seriously slow and extract power from the jet mechanism. There is also no teaching of modifying the device to have any of the remaining parts used in a jet injector. Thus, one of skill in the art would not find any teaching, suggestion, or motivation to use this very energy-inefficient system in a jet injector.

The subject matter of claim 24 is also patentably distinct from Richmond, which neither teaches nor suggests making the first stopper to substantially prevent any of the medicament contained in the cartridge from contacting the needle prior to the firing of the jet injector. The forwardmost stopper in Richmond does not keep the solution in compartment D from contacting the needle 30. Claim 24 provides the surprising advantage over Richmond that the sterility of any medicament within the cartridge can be maintained until the injector is fired. This is not possible in Richmond because compartment D is open to the atmosphere and forwardmost needle. Additionally, as disclosed in the specification of the present application, certain medicaments, such as those containing insoluble particles, tend to clog the needle if in contact therewith prior to injection, and claim 24 thus provides the additional surprising advantage over Richmond that these types of medicaments can be more reliably employed.

Claim 26 further defines that the medicament cartridge comprises only the two stoppers that contain the medicament there between, and claim 27 additionally recites that the medicament cartridge is configured such that all of the medicament in the cartridge is injected together. Claim 28 recites that the first stopper is free of any device to puncture another of the stoppers. The invention of each of these claims is contrary to the teaching of Richmond,

which requires many stoppers to inject different drugs, one after the other. Richmond teaches away from injecting all of the medicament together, and its purpose is defeated by providing only two stoppers that contain all of the medicament therebetween or by having the first stopper free of any piercing device. Thus, these claims are also patentably distinct from Richmond on their own merits.

With respect to Huber, this reference also has several teachings that make it incompatible with, and that provide no teaching, suggestion, or motivation of, replacing the manually operated plunger with the required high energy firing device of a jet injector. For instance, Huber teaches an aspirating syringe which is designed to aspirate from the injection site prior to injecting so that the aspirated matter is visible within the syringe. In a jet injector, any injecting needle is not long enough to reach the injection site by definition, because the jet itself forces the medicament deeper than the needle.

Additionally, as described in column 4 of the Huber patent, the structure of the syringe and the teaching is for allowing the syringe to be held aiming upward to then apply pressure against the plunger to cause liquid to enter the dry forward compartment. The syringe is then meant to be shaken, and the medication must be allowed to dissolve. Then residual air is then expelled through the needle. After that, the aspiration takes place, possibly more than once. All of these various required movements of the plunger, Huber further teaches away from jet injectors, in which activation of the plunger is by a high power energy source that moves the plunger quickly and sufficiently to perform an injection. It is not clear from these complex movements and long periods of time required for and between each plunger movement, such as to reconstitute the medication, could be made to work with the fast activation and fast firing mechanism of a jet injector. As a result, the present claims are not anticipated nor rendered obvious over Huber.

The subject matter of claim 24 is also patentably distinct from Huber. Huber neither teaches nor suggests making the first stopper to substantially prevent any of the medicament contained in the cartridge from contacting the needle prior to the firing of the jet injector, as defined in claim 24. The only stopper 46 that is pierce by needle 14 is pierced only after the stopple 39 is pierced, and thus after the medicament is in contact with the needle. As discussed above, many steps need to take place prior to the Huber syringe being ready to inject the medicament. Claim 24 provides the surprising advantage of allowing sterility of the medicament within the cartridge until the moment of firing, which is neither possible nor desired in Huber, which requires the various steps, including air release,

dissolving of the medication, and aspiration prior to injection. Additionally, as disclosed in the specification of the present application, certain medicaments, such as those containing insoluble particles, tend to clog the needle if in contact therewith prior to injection, and claim 24 thus provides the surprising advantage over Huber that these types of medicaments can more reliably be employed.

With respect to Vetter, the rejection alleges that Vetter teaches insoluble particles, based on the disclosure of lyophilizing off the solution in column 3. As explained in the application's specification, medicaments containing insoluble particles often clog injection needles if in contact therewith prior to injection, which is especially critical in a jet injector, since jet injectors rely on a clean and predictable injection conduit to properly form and expel the high speed and high energy jet. The Vetter disclosure teaches that the medicament is in solution, and the lyophilizing occurs from the solution. Thus, this is contrary to the teaching of insoluble particles.

Furthermore, Richmond requires injecting a series of drugs one after the other. Richmond is not readily modifiable to use the system of Vetter and still maintain this capability. Such a modification is not possible without undue additional experimentation and invention. For example, if the Vetter open groove 19 were used in Richmond, the various drugs would start combining with each other and would not be sequentially injectable. Thus, there is no motivation to combine these references, and any combination would defeat the Richmond teaching and renders it inoperative for it intended purpose.

With respect to Tanaka, this reference does not remedy the deficiencies of Huber, and together do not result in the invention of any of the present claims.

Consequently, as indicated above, it is respectfully requested that the final status of the rejection be withdrawn. All claims are consequently presently believed to be in condition for allowance.

Respectfully submitted,

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